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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/311,428	05/13/1999	JOHN O'CONNOR	54205-B/JPW/	1219

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EXAMINER
COOK, LISA V

ART UNIT	PAPER NUMBER
1641	18

DATE MAILED: 11/19/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/311,428	O CONNOR ET AL.	
	Examiner	Art Unit	
	Lisa V. Cook	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 August 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *81-91* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *81-91* is/are rejected.

7)☒ Claim(s) *81-91* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Continued Prosecution Application

1. The request filed on 12 August 2002 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/311,428 is acceptable and a CPA has been established. An action on the CPA follows.

Amendment Entry

2. Applicants' preliminary amendment-E filed in response to the Final Office Action mailed 10 October 2001 in Paper #17 is acknowledged. Applicants have canceled claims 67-76 and 78-80 without prejudice or disclaimer. New claims 81-91 have been added. Currently, claims 81-91 are pending and under consideration.

OBJECTIONS WITHDRAWN

Oath/Declaration

3. Applicant's new oath or declaration submitted 18 April 2002 in paper #15 has corrected the following objections to the oath: The oath filed 12/01/99 and 2/28/00, list priority document No. 09/017,976 and PCT/US99/02289 with corresponding filing date as 3 February 1999. The correct filling date for Application No. 09/017,976 should be 3 February 1998. The objection is withdrawn.

OBJECTIONS MAINTAINED

Drawings

4. The drawings in this application have been objected to by the Draftsperson under 37 CFR 1.84 or 1.152 (see PTO-948). Applicant is required to submit a proposed drawing correction in reply to this Office action. However, formal correction of the noted defect can be deferred until the application is allowed by the examiner. Applicants have deferred revised drawing corrections until allowance of the instant application. The objection is maintained.

Specification

5. Applicant's will submit a corrected version of the paragraphs containing references to trademarks in due course. Until receipt of applicant's response the objections are maintained. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. 'Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

6. The use of trademarks has been noted in this application (For example see "Superose" on page 12, line 18). They should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks. Superose has not been capitalized in the disclosure. The objection remains.

REJECTIONS WITHDRAWN

Claim Rejections - 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 71-74 (new claims 83-86) are withdrawn from rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification has been updated to include complete deposit information for the deposit of hybridoma cell lines and monoclonal antibodies B108, B109, B152, and B207 in accordance with 37 CFR 1.801-1.809.

Amendment of the specification to recite the current practice requiring that a statement concerning all restrictions upon public access to the deposit will be irrevocably removed upon the grant of a patent on this Application and that the deposit will be replaced if viable samples cannot be dispensed by the depository made in the instant Application. In re Lundak, 773 F.2d.1216, 27 USPQ 90 (CAFC 1985) and 37 CRF §§ 1.801-1.809 for further information concerning deposit practice. Accordingly, the rejection is withdrawn.

Please note the following rejections are MOOT because claims 67-76 and 78-80 have been cancelled and the new claims are directed to an EP-hCG molecule that does not find support in the instant claims.

Double Patenting

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 81-91 (previously claims 67-80) are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 53-81 of copending Application No. 09/017,976. Although the conflicting claims are not identical, they are not patentably distinct from each other because The instant claims are not patentably distinct from the claims found in co-pending Application No. 09/017,976 because the claims employ the same method steps that encompass obvious modifications in assay design while utilizing the exact same reagents (i.e. molecular isoforms of hCG, non-nicked hCG, B152, B109, and B108). Although one preamble recites "A method of predicting pregnancy outcome – 09/017,976" and the other preamble recites "A method of detecting gestational trophoblast malignancy – 09/311,428", the preambles are encompass the same subject matter and are not given patenatable weight. See MPEP 2111.02 Weight of Preamble

PREAMBLE IS NONLIMITING UNLESS IT BREATHES LIFE AND MEANING INTO THE CLAIM
The preamble is not given the effect of a limitation unless it breathes life and meaning into the claim. In order to limit the claim, the preamble must be "essential to point out the invention defined by the claim." Kropa v. Robie, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951) (discussed below). In claims directed to articles and apparatus, any phraseology in the preamble that limits the structure of that article or apparatus must be given weight. In re Stencel, 828 F.2d 751, 4 USPQ2d 1071 (Fed. Cir. 1987) (discussed below). On the other hand, a preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. In re Hirao, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) (process claims, discussed below); Kropa v. Robie, 187 F.2d at 152, 88 USPQ at 481 (claims directed to apparatus, products, chemical structure, etc., as discussed below).
In In re Hirao, 535 F.2d 67, 190 USPQ 15 (CCPA 1976), the claim preamble set forth "A process for preparing foods and drinks sweetened mildly, and protected against discoloration, Streckler's reaction, and moisture absorption." The body of the claim recited two steps directed to the formation of high purity maltose and a third step of adding the maltose to foods and drinks as a sweetener. The court held that the preamble was only directed to the purpose of the process, the steps could stand alone and did not depend on the preamble for completeness.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

10. Claims 81-91 (previously claims 67-80) are provisionally rejected under 35 U.S.C. 103(a) as being obvious over copending Application No. 09/017,976 which has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the copending application, it would constitute prior art under 35 U.S.C. 102(e) if patented. This provisional rejection under 35 U.S.C. 103(a) is based upon a presumption of future patenting of the conflicting application. This provisional rejection might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the copending application was derived from the inventor of this application and is thus not the invention "by another," or by a showing of a date of invention for the instant application prior to the effective U.S. filing date of the copending application under 37 CFR 1.131.

For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Please Note: In the following rejections, the detection of gestational trophoblast malignancy is seen as intended use for methods detecting and evaluating non-nicked hCG and molecular isoforms of hCG in pregnancy/gestational diagnosis.

I. Claims 67-70, 73, 74, and 75-80 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ellish et al. (Human Reproduction, 1996).

Ellish et al. teach an immunoradiometric assay which has two solid-phase immobilized capture antibodies and one detection antibody to study early pregnancy loss.

Ellish et al. employ B109 to capture the non-nicked hCG molecule and B207 to capture free β subunit and hCG free β core fragment. Ellish et al. utilized B108 as the radioactive labeled detection antibody. (page 4074, column 2) .

Although this reference does not specifically state that the assay will be repeated in order to determine continued high ratios as required in the repeating step (4) it is well known to those with ordinary skill in the art that sampling at various points with multiple parameters is commonly used for in assay systems. Methods for determining this data can be achieved by procedures known to those of ordinary skill in the art..

It would have been prima facie obvious to one of ordinary skill in the art to repeat the sample analyses on samples sets and compare them to each other to evaluate the end result s in the method demonstrated by Ellish et al. with a reasonable expectation of success and little additional labor because this information can be easily determined utilizing protocols/data points/etc. that are already being used in their methods, such as range sampling on various days of gestation (i.e. HCG concentrations on day 3, day 2 – see Abstract).

The repetition of samples in the method of Ellish et al. would have been an obvious modification to the existing method. One of ordinary skill in the art would utilize various comparative calculations for the resulting data sets to evaluated the particular diagnosis. These calculations are routine optimizations that are almost always determined and used in immunoassay studies. Unless the result obtained in the instant application is a significant and unexpected difference over the prior art, it would have been prima facie obvious for one of ordinary skill in the art to repeat sample analysis on a given sample in the given method to determine the unknown diagnosis as a means of optimizing the assays provided by the art.

II. Claims 67-70, 72, 74, and 75-80 are rejected under 35 U.S.C. 103(a) as being unpatentable over Birken et al. (Endocrinology 1993).

Birken et al. disclose a two-site immunoradiometric assay to evaluate immunoptency of nicked hCG. Birken et al. further teach a capture antibody that specifically binds non-nicked hCG (intact hCG heterodimer) along with a detecting (tracer) antibody. The capture antibody is B109 and the I125 radiolabeling antibody is B108. (See page 1391, column 1).

Although this reference does not specifically state that the assay will be repeated in order to determine continued high ratios as required in the repeating step (4) it is well known to those with ordinary skill in the art that sampling at various points with multiple parameters is commonly used for in assay systems. Methods for determining this data can be achieved by procedures known to those of ordinary skill in the art..

It would have been prima facie obvious to one of ordinary skill in the art to repeat the sample analyses on samples sets and compare them to each other to evaluate the end result s in the method demonstrated by Birken et al. with a reasonable expectation of success and little additional labor because this information can be easily determined utilizing protocols/data points/etc. that are already being used in the cited method. The repetition of samples in the method of Birken et al. would have been an obvious modification to the existing method. One of ordinary skill in the art would utilize various comparative calculations for the resulting data sets to evaluated the particular diagnosis. These calculations are routine optimizations that are almost always determined and used in immunoassay studies.

Unless the result obtained in the instant application is a significant and unexpected difference over the prior art, it would have been prima facie obvious for one of ordinary skill in the art to repeat sample analysis on a given sample in the given method to determine the unknown diagnosis as a means of optimizing the assays provided by the art.

III. Claims 67-70, 72, 74, and 75-80 are rejected under 35 U.S.C. 103(a) as being unpatentable over by O'Connor et al. (Cancer Research, 1988).

O'Connor et al. disclosed assays to evaluate hCG function. O'Connor et al. specifically teach immobilized capture antibodies via B108 or B109 coated solid phase materials which specifically bind non-nicked hCG. (See page 1362, column 1). Although this reference does not specifically state that the assay will be repeated in order to determine continued high ratios as required in the repeating step (4) it is well known to those with ordinary skill in the art that sampling at various points with multiple parameters is commonly used for in assay systems. Methods for determining this data can be achieved by procedures known to those of ordinary skill in the art..

It would have been prima facie obvious to one of ordinary skill in the art to repeat the sample analyses on samples sets and compare them to each other to evaluate the end results in the method demonstrated by O'Connor et al. with a reasonable expectation of success and little additional labor because this information can be easily determined utilizing protocols/data points/etc. that are already being used in their methods, such as range sampling to determine Inter- and Intra-assay variation (1362 – Quality Control Evaluation of Immunoassay).

The repetition of samples in the method of O'Connor et al. would have been an obvious modification to the existing method. One of ordinary skill in the art would utilize various comparative calculations for the resulting data sets to evaluated the particular diagnosis. These calculations are routine optimizations that are almost always determined and used in immunoassay studies.

Unless the result obtained in the instant application is a significant and unexpected difference over the prior art, it would have been prima facie obvious for one of ordinary skill in the art to repeat sample analysis on a given sample in the given method to determine the unknown diagnosis as a means of optimizing the assays provided by the art.

NEW GROUNDS OF REJECTION NECESSITATED BY AMENDMENT

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. Claims 81-91 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

All the claims are directed to the measurement of complexes formed between "EP-hCG" and an antibody. However the term "EP-hCG" is not found in the disclosure. Applicant is invited to show support fro the term in the instant specification.

13. Claims 81, 82 and 87-91 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The written description in this case only sets forth a method of detecting gestational trophoblast malignancy via combinations of antibodies produces from hydriboma cell lines B152, B109, B108, and B207. Therefore the written description is not commensurate in scope with the claims drawn to the utility of any two or three antibodies in combination to measure gestational trphoblast malignancy.

Further because the claims merely read on the detection of an EP-hCG which is not clearly identified in the disclosure, there is no clear indication as to what is actually being measured. Due to the lack of written description of the structure or identity of the EP-hCG molecule, one cannot generate other antibodies to the specific EP-hCG molecule of the instantly claimed invention. Therein the specific antibodies disclosed in the specification are required to insure detection of the appropriate molecules having direct correlation to gestational trophoblast malignancy.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*.

The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (*See Vas-Cath* at page 1116). Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC 112 is severable from its enablement provision (see page 115).

With the exception of antibodies produces from hydriboma cell lines B152, B109, B108, and B207, the skilled artisan cannot envision the detailed structure of the encompassed antibodies and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it.

The antibody itself is required. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016.

Furthermore, In *The Reagents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of a compound/seq.id/etc. by only their functional activity does not provide an adequate written description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of molecules, usually defined by a sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description ...'requires a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention".

However, no disclosure, other than antibodies produces from hydriboma cell lines B152, B109, B108, and B207 is made in the specification. This is insufficient to support the generic claims as provided by the Interim Written Description Guildlines published in the June 15, 1998 Federal Register at Volume 63, Number 114, pages 32639-32645.

Therefore only methods utilizing the antibodies produced from hydriboma cell lines B152, B109, B108, and B207, but not any and all antibodies would meet the full breadth of the claims as required by the written description provision of 35 USC 112, first paragraph.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

14. Claims 81-91 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 81 and 82 are vague and indefinite. Specifically, in claims 81 and 82 the method of detecting gestational trophoblast malignancy is conducted via a binding complex involving "EP-hCG". However, EP-hCG is not defined by the claims or the specification. As recited the metes and bounds of the claim cannot be determined. Therein one of ordinary skill in the art would not be appraised of the scope of the instant invention.

Allowable Subject Matter

15. Currently claim 83 (previously 71) is free of the prior art of record which neither teach or suggest the instant molecular isoform of hCG or a characteristic epitope thereof defined by the specific binding of monoclonal antibody B152. Claims 84-86 remains objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The prior art of record teaches the antibodies cited in claims 84-86 however the multiple utility of the antibodies in the claimed method is not taught.

16. For reasons aforementioned, no claims are allowed.

17. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Group 1641 Fax number is (703) 308-4242, which is able to receive transmissions 24 hours/day, 7 days/week.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa V. Cook whose telephone number is (703) 305-0808. The examiner can normally be reached on Monday-Friday from 8:00 AM - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (703) 305-3399.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Christopher L. Chin

CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP ~~1800~~ 1641

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CM1-7B17
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11/13/02